ANNUAL PROGRAM EVALUATION REPORT

STATE: Maine

A. Overall Program Status

Growing Area Classification Element

The Maine Department of Marine Resources (DMR) Growing Area Program, administered by the Public Health Division, does not meet all of the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO).

Control of Harvest (Patrol) Element

The Maine DMR Patrol Program, administered by the Bureau of Marine Patrol (BMP), meets the requirements of the NSSP Model Ordinance.

Plant and Shipping Sanitation Element

The Maine DMR Plant Sanitation Program, administered by the Public Health Division, does not meet all of the requirements of the NSSP Model Ordinance.

Laboratory Element

The Maine DMR Shellfish Laboratories currently "conforms" to the requirements of the NSSP Model Ordinance. In May 2008, the water quality and marine biotoxin laboratories at the Lamoine State Park and the water quality and marine biotoxin laboratories located in West Boothbay Harbor were evaluated.

Vibrio Risk Management Plan Implementation Element

The State's voluntary *Vibrio* Risk Management Plan implementation efforts administered by the DMR currently meet the minimum requirements of the NSSP Model Ordinance.

B. Status of Deficiencies Identified during a Program Element Evaluation

Growing Area Classification Element

There were five program wide deficiencies related to the Maine DMR Water Quality Classification Program noted during the annual evaluation. The deficiencies are listed below:

i. During the review of the growing area reports it was noted that some of DMR's twelve-year Sanitary Survey reports were not completed in accordance with the requirements of the NSSP Model Ordinance for the following growing areas:

EU- St. Croix River

- There is no discussion of river discharge volume/seasonality for the St. Croix River. There is a description of the size of the drainage basin. [MO Chapter IV@.01 (A.)(1.) (c.)]
- There is no summary discussion of the effects of the river discharge on the growing area (dilution, dispersion, time of travel, salinity, depth and stratification characteristics and discussion concerning effects of pollution distribution and hydrographic factors on water quality). The rainfall, tide and wind sections do cover the effects on water quality in the growing area but there is no summary at the end to encompass all four (rainfall, tide, wind, river discharge). [MO Chapter IV@.01A.(1.) (c.) and (d.)]
- There is no data presentation, maps or conditional area management plan presented for a new proposed (reclassification from prohibited to conditionally approved on April 11, 2011) conditionally approved area in Lewis Cove, Perry. The area was downgraded from approved to prohibited as a result of the 2009 end of year data review. [MO Chapter IV@.03 (C.)(1.) and (2.)]
- There is no section for Interpretation of Data in Determination of Classification. [MO Chapter IV@.01 (A.)(1.) (d.)]

WL- New Meadows River

- There is no map or chart showing the location of major sources of actual or potential pollution in the survey area for domestic wastes identified during the shoreline survey, marinas/mooring fields, streams, agricultural activities, or domestic animals and wildlife. [MO Chapter IV@.01 (D.)(2.)(d.)(i.)]
- The Hydrographic and Meteorological Assessment section does not contain all the required elements for Rainfall; e.g. amount, when (time of year) or frequency of significant rainfalls. Additionally, stations classified approved (WL11, WL12, WL20, WL21, WL22, WL26, WL36.7 and WL77 in Table 5) show a marked increase in P90 scores, in excess of the NSSP approved standard but there is no evaluation or further discussion in the report on what impact rainfall has on the area. [MO Chapter IV@.01A. (1) (c.) and (d.)]
- There is no summary discussion of the effects of rainfall, tide, and wind on the growing area (dilution, dispersion, time of travel, salinity, depth and stratification characteristics and discussion concerning effects of pollution distribution and hydrographic factors on water quality). The sections do cover the effects on water quality in the growing area but there is no summary at the end to encompass all three (rainfall, tide, and wind). [MO Chapter IV@.01 (1.)(c.)]

- There is no sampling plan and justification (adverse condition sampling and/or random sampling). [MO Chapter IV@.02]
- There was no sample data analysis or presentation sorting the data by environmental pollution condition. [MO Chapter IV@.01 (A.) (1.) (d.)]
- There is an interpretation of data and a determination of classification for Browns Cove, West Bath and Long Cove, West Bath. There is no conclusion section which includes the interpretation of data and determination of classification including a discussion of how actual or potential pollution sources, wind, rainfall, tide, etc. affect or may affect water quality and address the effects of meteorological and hydrographic conditions on bacterial loading and variability in the bacteriological data and causes. [MO Chapter IV@.01 (A.) (1.) (d.)]
- A 'small marina' located at Hermit Island Campground was not evaluated. [MO Chapter IV@.01 (D.)(1.) (a.)]

<u>WS-Medomak River</u>

- There is no date mentioned of when the last sanitary survey was completed. [MO Chapter IV@.01 (C.)(1.)]

ii. During the review of the growing area reports it was noted that one of DMR's triennial evaluation reports were not completed in accordance with the requirements of the NSSP Model Ordinance as follows:

<u>WI-Western Casco Bay</u>

During the review of the triennial report for Growing Area WI it was noted that the DMR did not include all sample stations in the review of water quality section [MO Chapter IV.@01 (C.)(3.) (a.)(i.)]; there was no reevaluation of all pollution sources previously identified to fully evaluate any changes in the sanitary conditions of the growing area [MO Chapter IV.@01 (C.)(3.) (a.)(iii.)] and there was no summary statement which analyzed all the elements of the triennial or a determination that the existing growing area classification is correct or needs to be revised [MO Chapter IV.@01 (C.)(3.) (a.)(iv.)].

Specifically, in the Triennial Evaluation of Growing Area WI, the review of water quality did not include the sample stations associated with the wastewater treatment plant (WWTP) conditional area; stations WI 41, 51, 51.5, 53, 54, 55.2, 55.5, 56, 58.5 and 58.8. The executive summary references the removal of an OBD in Portland but it is not referenced or assessed in the Domestic Waste section of the report. The Agricultural Activities section specifically stated: "as part of this triennial report, agricultural activities and associated waste were noted but not fully evaluated". The Aquaculture and Wet Storage Activities section states that there are twelve aquaculture lease sites but does not contain an evaluation of their actual/potential impact on the growing area. There is no

summary statement which analyzes all the elements of the triennial evaluation (new pollution sources, existing pollution sources, and review of water quality) and makes a determination that the existing growing area classification is correct or needs to be revised.

iii. During the review of the growing area reports it was noted that some of DMR's annual evaluation reports were not completed in accordance with the requirements of the NSSP Model Ordinance for the following growing areas:

<u>EQ- Little Kennebec River</u>

- During the review of the growing area report for Area EQ it was noted that the DMR established an Approved/Prohibited boundary line around a failing water quality station (EQ5.1) and the boundary line was moved downstream to a station with only 10 data points and not the 30 data points required for classification [MO Chapter IV@.02 (F.)(6.) (b.)(v.)]

Specifically, one sample station (EQ 5.1) failed to meet the Approved standard at the Prohibited area/Approved area boundary line and a station was re-activated (EQ 5.6) to act as a new boundary station. At the end of 2010, there were only 10 data points at station EQ 5.6 and not the required 30 data points for classification. It is not clear, based on the data presented, that the location of the boundary line affords the necessary buffer. The boundary lines should be reassessed scientifically and the new line should be moved to the most appropriate location to protect public health.

- During the review of the annual report for Growing Area EQ it was noted that the DMR did not conduct and document field observations of pollution sources by conducting a drive-through survey or observations made during sample collection. [MO Chapter IV @01 (C.)(5.) (a.)] Specifically, there is no reference in the report regarding observations made during a drive-through survey or observations made during sample collection.

iv. During the review of the existing conditional area management plan State annual reviews it was noted that some of DMR's conditional areas were not re-opened or sampled in accordance with the requirements of the NSSP Model Ordinance for the following growing areas:

<u>EG- Union River Bay and the western portion of Mount Desert Island</u>

- DMR did not collect shellfish samples to justify reopening after a closure event in a conditional area based on wastewater treatment plant function. These samples were necessary to show that sufficient time had elapsed to allow shellstock to reduce pathogens that might be present to acceptable levels after the event [MO Chapter IV@.03 (A.)(5.) (c.)]. Specifically, the growing area EG

WWTP conditional area management plan annual review of the conditional area management plan did not include shellfish samples as part of the re-opening criteria of the area. The report states: "During 2010, there were 15 internal and 10 external bypass events resulting in 6 closures of the conditional area for 117 days. Area 40B stations EG2, EG4, EG5, EG7, EG16.5, EG17 due to performance of Ellsworth WWTP (sic)." No additional re-opening criteria, no closure dates or re-opening dates were present in the triennial report or the conditional area management plan annual review.

WI- Western Casco Bay

- DMR did not collect shellfish samples to justify reopening after a closure event in a conditional area based on wastewater treatment plant function. These samples were necessary to show that sufficient time had elapsed to allow shellstock to reduce pathogens that might be present to acceptable levels after the event [MO Chapter IV@.03 (A.)(5.) (c.)]. Specifically, DMR's annual review for the growing Area WI, WWTP conditional area management plan did not include shellfish samples as part of the re-opening criteria of the area after a closure occurred on October 11, 2010.

- During the review of the WWTP annual review of conditional management plan for growing area WI it was noted that DMR's water sampling regime for monitoring the WWTP conditional area does not comply with the requirements of the NSSP Model Ordinance. Specifically, the criteria in the conditional area management plan review states; "This conditional area management plan requires the monitoring stations to be sampled a minimum of six times when the area is in the open status. All stations in the Cousins River WWTP conditional area were collected 6 times when in the open status in 2008-2010." However, the MO requires that, when the conditional management plan is based on the operation and performance of a WWTP, monthly water samples are required when the growing area is in the open status of its conditional classification [MO Chapter IV@03 (C.)(3)(b)(ii)].

- During the review of the conditional area management plan for Growing Area WI based on a seasonally closed area due to the presence of a marina, it was noted that the water sampling regime for monitoring the marina conditional area is not done in accordance with the requirements of the MO. Specifically, DMR's Falmouth Foreside marina seasonal area conditional management plan annual review report contained the following statement: "This conditional area management plan requires the monitoring stations to be sampled a minimum of six times when the area is in the open status. All stations in the Falmouth Foreside conditional area were collected 6 times when in the open status in 2007 and 2008." The sampling criterion quoted in the Growing Area WI – Falmouth Foreside marina conditional area is not in accordance with the requirements of the MO, which states; "When the conditional management plan is based on the

absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacterial standard for the open status are collected when the growing area is in the open status". Additionally, the DMR report presented no data for 2010 to verify the requirement that at least three of the water samples were collected in the open status. [MO Chapter IV@03 (C.)(3.) (b.)(i.)]

v. During the review of six (6) new conditional area management plans for new re-classified seasonal conditional areas (Growing Area EF – Herrick Bay, Brooklin and Blue Hill Salt Pond, Sedgwick/Brooklin, Growing Area EU – Lewis Cove, Perry, Growing Area WL – Long Cove, West Bath, Growing Area WI – Broad Cove, Cumberland/Yarmouth and Growing Area WW – Stockton Harbor, Stockton Springs) it was noted that the DMR did not include all of the necessary elements for conditional area management plans as required in the NSSP. [MO Chapter IV @03. (C.)]

<u>EF- Blue Hill Bay</u>

- Specifically, Growing Area EF – Herrick Bay, Brooklin did not include all of the required elements of a conditional area management plan; including, a description of the plan for monitoring water quality including numbers and frequency [MO Chapter IV@.03 (C.)(3.) (b.)]; a description of how the closed status will be implemented [MO Chapter IV@.03 (C.)(2.) (f.) through (h.)]; a description of the criteria that must be met prior to reopening the area [MO Chapter IV@.03 (C.)(c.)(i.) thru (iv.)]; or a commitment to reevaluate the management plan at least annually, using the requirements in the NSSP MO [MO Chapter IV@.03 (C.)(3.) (a.)].

- Growing Area EF – Blue Hill Salt Pond, Sedgwick/Brooklin did not include all of the required elements of a conditional area management plan, including; a description of how the closed status will be implemented [MO Chapter IV@.03 (C.)(2.) (f.) through (h)]; a description of the criteria that must be met prior to reopening the area [MO Chapter IV@.03 (C.)(c.)(i.) through (iv.)]; or a commitment to reevaluate the management plan at least annually, using the requirements in the NSSP MO [MO Chapter IV@.03 (C.)(3.) (a.)].

- Growing Area WL – Long Cove, West Bath did not include all of the required elements of a conditional area management plan, including; data to show that the seasonal event is predictable and sufficient to establish meaningful performance standards for a growing area placed in conditional classification [MO Chapter IV@.03 (C.)(2.) (b.)]; a description of the plan for monitoring water quality including numbers and frequency [MO Chapter IV@.03 (C.)(3.) (b.)]; no clear statement that when performance standards are not met, the growing area will be placed in the closed status [MO Chapter IV@.03 (C.)(2.) (c.)(i.)]; the

procedures and methods used to notify the patrol agency [MO Chapter IV@.03 (C.)(2.) (f.)]; name of the responsible patrol agency [MO Chapter IV@.03 (C.)(2.) (g.)]; or response time between closure and notification to patrol or description of patrol activities to enforce the closed status [MO Chapter IV@.03 (C.)(2.) (h.)].

- Growing Area WI – Broad Cove, Cumberland/Yarmouth did not include all of the required elements of a conditional area management plan, including; a description of the plan for monitoring water quality including numbers and frequency [MO Chapter IV@.03 (C.)(3.) (b.)]; a description of how the closed status will be implemented [MO Chapter IV@.03 (C.)(2.) (f.) through (h.)]; or a description of the criteria that must be met prior to reopening the area [MO Chapter IV@.03 (C.)(2.) (b.)(i.) and (ii.)].

- Growing Area WW – Stockton Harbor, Stockton Springs did not include all of the required elements of a conditional area management plan, including; a map showing the area's boundaries [MO Chapter IV@.03 (A.)(3.) (a.) and (b.)]; data to show that the seasonal event is predictable and sufficient to establish meaningful performance standards for a growing area placed in conditional classification [MO Chapter IV@.03 (C.)(2.) (b.) (i.) and (ii.)]; or a description of how the closed status will be implemented and enforced [MO Chapter IV@.03 (C.)(2.) (f.) through (h.)].

A corrective action plan was requested for the program deficiencies noted above. Any additional follow-up required prior to the FY 2012 evaluation will be based on the submitted action plan. Once the action plan has been reviewed, the US Food & Drug Administration (FDA) and DMR will discuss the most appropriate follow-up to the deficiencies.

Control of Harvest (Patrol) Element

No deficiencies were cited during the FY 2011 program evaluation for the DMR Control of Harvest (Patrol) Element per Chapter VIII of the NSSP MO. No corrective action plans were requested; no additional follow-up is required. The next evaluation is scheduled for FY 2012.

Plant and Shipping Sanitation Element

An administrative deficiency was cited during the FY 2011 DMR Plant and Shipping Sanitation Element evaluation per Chapter I of the NSSP MO. The evaluation revealed that the DMR did not meet the minimum required inspection frequency for certified dealers pursuant to NSSP MO Chapters X, XI and XIII during the period of 2009 through 2010. In particular, file review for thirteen firms selected found that four (4) Shucker Packers and one (1) Shellstock Shipper was not inspected at the minimum required frequency:

- In 2010, DMR was short two of the four required annual inspections for the Shucker – Packer, Carver Shellfish (ME-60-SP);

- In 2009, DMR was two short and in 2010, DMR was one short of the four required annual inspections for the Shucker – Packer, Maine Shellfish (ME-100-SP);

- In 2009, DMR was two short of the four required annual inspections for the Shucker – Packer, Dennison's Seafood (ME-33-SP);

- In each of the years 2009 and 2010, DMR was one short of the four required annual inspections for the Shucker – Packer, Young's Lobster Pound (ME-222-SP);

- In 2009, DMR was one short of the two required annual inspections for the Shellfish Shipper, Atlantic Shellfish (ME-150-SS).

A corrective Action Plan was requested and received for the deficiency. The DMR reported that they are currently on track to do the required number of plant inspections for 2011-2012 and they are cross training an additional staff member within the Division to assist with inspections. The DMR has started in-field training and the staff member will take a HACCP course and the next available FDA standardization course. No additional follow up is necessary and the next biennial evaluation is scheduled for FY 2013.

Laboratory

The Maine Growing Area Program is supported by two laboratories, the DMR Boothbay Harbor (BBH) water quality (WQ) and marine biotoxin monitoring laboratory and the Lamoine (LAM) water quality and marine biotoxin monitoring laboratory. Both laboratories were evaluated in May 2008 by Linda Chandler, FDA Laboratory Evaluation Officer (LEO). The FY 2008 evaluation focused on the shellfish microbiological and marine biotoxin monitoring programs regarding seawater and shellfish meats, including procedures and methods used by both laboratories. The water quality monitoring labs utilize the membrane filtration method using mTEC agar (MF/mTEC). DMR changed to this method in August 2006 following comparative testing with the original method used by DMR and following its' adoption as a new method by the 2005 ISSC for fecal coliform testing of seawater. The marine biotoxin labs utilize the mouse bioassay method to detect saxitoxin in shellfish meats, the cause of Paralytic Shellfish Poisoning (PSP). At present both laboratories were found conforming to the requirements of the NSSP Model Ordinance. Laboratory evaluations are required triennially; the next evaluation was due to be conducted in 2011.

<u>Water Quality Monitoring Program</u>

Mercuria Cumbo, the State Laboratory Evaluation Officer, is the Laboratory Manager for the water quality program for the LAM water quality laboratory. Ms. Cumbo works on a daily basis from the LAM WQ Laboratory with Desiree Hills, Marine Resource (MR) Technician and additional support from the Growing Area staff, two MR Scientists and two MR Specialists. The BBH WQ Laboratory staff members are Cathy Vining, Lead Microbiologist , Gail Parsons, Microbiologist and two MR Technicians, Ed Their and Heather Gilbert. The MR Technicians in both laboratories work both in the laboratory and in the field as needed.

The two laboratories analyze samples for the growing area program and the dealer certification program. Tests are performed on seawater, process water, well water and shellfish using both membrane filtration and multiple tube fermentation methods (MPN) as required by the NSSP MO. The growing area program utilizes the Systematic Random Sampling regime. In 2010 both laboratories analyzed a total of 13,895 seawater samples using the MF/mTEC method which was an increase of 1,257 samples from 2009. Additionally, 344 dealer water samples for total coliforms and E. coli using MPN procedures and 102 shellfish samples for fecal coliforms using the APHA MPN method were analyzed.

Both laboratories are now equipped for testing Male Specific Coliphage (MSC) (viral indicator for waste water treatment plant (WWTP) sewage discharges) using the NSSP approved method. MSC is performed on any shellfish samples submitted to the laboratories for fecal coliform testing as time permits. Also as time permits, this testing will be expanded to include wastewater treatment plant effluents and to collect background data for shellfish throughout all growing areas in Maine.

Marine Biotoxin Monitoring Program

The waters of the Gulf of Maine are the host to several species of phytoplankton which could produce biotoxins. The most severe problems result from blooms of *Alexandrium sp.*, which cause PSP. Maine waters are also suitable for the growth of *Dinophysis sp.*, and *Prorocentrum lima*, both which are known to cause Diarrhetic Shellfish Poisoning (DSP) in eastern Canada and in other parts of the world. Likewise, *Pseudo-nitzschia sp.* is known to cause Amnesiac Shellfish Poisoning (ASP) in eastern Canada and other parts of the world. The Maine Marine Biotoxin Monitoring Program focuses on monitoring for PSP in shellfish meats, while relying on toxicity information from eastern Canada and phytoplankton monitoring in Maine waters to provide a warning for the potential presence of DSP or ASP. The PSP monitoring program in Maine is defined in detail in the Biotoxin Quality Assurance Plan, which can be found in both Maine DMR Biotoxin Labs, as well as on line at:

http://www.maine.gov/dmr/rm/public_health/biotoxinmonitoring.htm

Ms. Darcie Couture is the Director of the Marine Biotoxin Monitoring Program. Ms. Nicole DeLisle, Scientist I, reports to her at the West Boothbay Harbor Lab and Ms.

Alexandra Rohrer, Scientist I, reports to her at the Lamoine Lab. Each lab is also staffed by a permanent Seasonal Conservation Aide and one or more temporary Seasonal Conservation Aides.

Sample collection for PSP is done by the Scientists and Conservation Aides. Occasionally, water quality staff, marine patrol officers, area biologists, seafood inspectors and other specially licensed personnel assist in the collection of samples. Sampling for PSP is usually conducted from mid March into late October for most species, although surf clam sampling may occur year-round, as needed.

The Director of the Marine Biotoxin Monitoring Program oversees and guides the sampling scheduling, reviews all toxicity data, and is responsible for implementing the Administrative Procedures Act for promulgation of shellfish harvesting area closures and openings. The Director also maintains close contact with other states and countries regarding current toxicity levels, represents the Department at meetings and serves as the contact person for media and industry.

C. Specific Information on Illnesses, Outbreaks and/or Recalls

Maine shellfish in interstate commerce were not associated with any illnesses, outbreaks and/or recalls in 2010.

D. State Program Accomplishments

Growing Area Element

- On October 12, 2011 DMR then-Acting Commissioner Patrick Keliher announced the promotion of Ms. Kohl Kanwit as the Director of the Public Health Division.

- Alison Sirois was hired as the Growing Area Program Manager on October 31, 2011.

- DMR sponsored an AmeriCorp volunteer during 2011. This individual was tasked with working closely on the Lower Kennebec and assisting other staff members in the Growing Area Program. DMR has secured funding for another AmeriCorp volunteer in 2012.

Control of Harvest (Patrol) Element

- The highlight of the MDMR accomplishments for FY 2011 is the continued fact that they maintained effective patrol monitoring of the shellfish harvest areas with a significant vacancy rate among the field officer staff. Although a minimum of 2632 patrols were required, a total of 5682 were completed.

- The application of technology to field personnel continues to greatly assist field officers with the most current information at their fingertips. FY 2009 marked the

final deployment of Mobile Data Terminals (MDT) that are now in service in every patrol vehicle and every major patrol vessel. The access to information and the ability to share that information with members of the industry continues to be a very effective tool in public outreach and patrol monitoring efforts.

Plant and Shipping Sanitation Element

- In October 2009, SSO Bruce Chamberlain attended the biennial Interstate Shellfish Sanitation Conference (ISSC) held in Manchester, New Hampshire.

- Bruce Chamberlain successfully completed Shellfish State Standardization training course FD241 given by FDA in Battle Creek, Michigan on November 2-3, 2010.

- Effective November 15, 2010, Melinda Madsen joined DMR's shellfish plant inspection unit.

Biotoxin

- Darcie Couture, Biotoxin Program Manager, worked on an extensive Single Lab Validation (SLV) for the Abraxis PSP ELISA kit, in cooperation with the state of New Hampshire, the FDA, and the ISSC. Darcie completed work on assessing multiple versions of the kit, using two different extraction methods, as well as three different shellfish species. Darcie presented preliminary results at the 2011 ISSC meeting in Seattle, Washington, and as a result, a version of the PSP ELISA kit using a rapid extraction method was approved by the ISSC for use in the FDA Dockside Testing Protocol for harvesting shellfish from federally closed waters. Darcie has six months to complete the remaining validation work and statistics, which will then be presented to the Lab Methods review Committee.

- Darcie Couture and Alison Sirois organized and hosted a meeting in Portland, Maine on November 1, 2011, with other state HAB managers in the New England region. Agenda topics included an assessment of each of the New England state programs, including strategies for HAB monitoring and testing, as well as identifying existing testing capacities for various marine biotoxins and identifying gaps and emerging needs. Meeting outcomes included a resolution from New Hampshire and Massachusetts to adopt and standardize the phytoplankton monitoring programs in their respective states to follow the protocols already in place in Maine, and there was a general consensus that establishing a regional lab with the capacity to serve all of the state programs in the area would be an optimal solution to the needs arising from current and future emerging HAB events.

- In the late summer and early fall of 2011, Darcie Couture worked with members of the Canadian Food Inspection Agency (CFIA) to establish protocols and procedures that would meet the requirements for a live whelk export market from Maine to Canada. The protocol involves establishing lot segregation and testing for both PSP

and ASP in whelks being held at the Maine dealer facility prior to export to Canada. To date, the final business arrangements between the Maine dealer and the Canadian dealer have yet to be finalized, but the testing protocols have been accepted by CFIA as adequate.

***Vibrio* Risk Management Plan Implementation Element**

- As part of the in-field industry compliance review component during the FY 2011 *Vibrio* Risk Management Plan implementation evaluation, three points of landing were visited by FDA and MDMR. During these visits, the authority verified that the firm's are abiding by the time temperature control stipulations cited in state regulations at the harvester level. The state has no plans to expand or modify their existing voluntary *Vibrio* Management Control Plan.

E. New or Emerging Problems

There were five new or emerging trends identified as a result of the Growing Area Classification Element evaluation, listed as follows:

- The DMR requested an interpretation from FDA in September 2010 and a request for an interpretation via email in November 2010 with a final interpretation from CFSAN in February 2011 regarding the relay of shellfish from prohibited areas for six (6) months regardless of size. FDA advised DMR that as per MO Chapter IV@.03 (E.)(2.)(a.) and MO Chapter IV@.03 (E.)(2.)(b.), market sized shellstock shall not be relayed from waters classified prohibited for the purpose of marketing. Only shellfish seed can be relayed from areas classified as prohibited for market for long term cleansing. Market size shellstock can however be removed from prohibited waters only for the purpose of depletion. Such removal for depletion must be done under direct supervision by the authority and none of the shellstock removed for depletion can ever be shipped to market.

- The DMR notified FDA that they are having internal discussions about how to handle an emerging issue regarding DMR's marine biotoxin monitoring program which came to light in early November 2010. Alexandrium/PSP is the major biotoxin of concern in Maine, but the DMR does occasionally see two other potentially toxin-producing species in Maine waters. One of these species is *Pseudo-nitzschia*, which can produce domoic acid, causing Amnesiac Shellfish Poisoning (ASP) when it occurs in shellfish. Although *Pseudo-nitzschia* has been observed in phytoplankton samples in low levels, regularly, in the fall and winter months for several years, it has occurred in exceptionally high numbers in fall 2010. The recent trend was reported to DMR's Biotoxin Program Manager, Darcie Couture from the state's Phytoplankton Monitoring

Network. The information provided by the volunteer monitors triggered the use of some Jellett rapid test ASP screening kits which produced a "positive" test for domoic acid from a phytoplankton sample in Bar Harbor.

The DMR Biotoxin labs are not currently equipped to run the ISSC approved method for testing shellfish for domoic acid. However, DMR has put a contingency plan into motion, and have shipped phytoplankton and shellfish samples to the NOAA lab in Charleston for further analyses. The results of these analyses will tell DMR if there is any domoic acid toxin in the shellfish, and if so, how much. If it turns out that Maine will have to begin initiating closures for ASP in Maine waters, then the DMR has already arranged to have the FDA laboratory run a small number of shellfish samples using the ISSC approved method to get us through a short emergency period. Additionally, if it turns out that this becomes a problem requiring a large, long-term monitoring effort, then DMR may be able to access NOAA Event Response funds to help the state pay for further testing in the short term. If it turns out that the Department is required to manage for ASP/domoic acid on a regular basis, then there will need to be some permanent budgetary solution for monitoring, which may include equipping and staffing the Biotoxin lab(s) and training staff to handle this testing.

- Land access for shoreline survey has become an issue in the past year. DMR staff members are more and more being denied access to the curtilage of properties for shoreline survey. Properties where the DMR have been denied access are reported to the local codes enforcement and the Department of Environmental Protection. There is a fear that as more properties become unavailable for shoreline survey and pollution source assessment the Department will need to make more closures to protect public health from potential pollution sources. Essentially, in order to successfully conduct shoreline surveys to stay in compliance with NSSP requirements, DMR may need to be granted legal authority to conduct inspections (within reason) without owner's permission, as long as their land is not posted "No Trespassing", an authority granted to DEP. If such legal authority is not granted, it may be impossible in some cases for DMR to complete the required shoreline survey work under the National Shellfish Sanitation Program.

- In response to inquiries made by the DMR, FDA in turn, requested the DMR provide the updated sanitary survey file that details and justifies the reclassification of the marina conditionally approved area in the Harraseeket River, Freeport, Growing Area WJ on August 30, 2011 and September 26, 2011 to the FDA regional shellfish specialist for review and concurrence [per M.O. Section II, Chapter IV @.01 (A.)(4.)]. The concern remains that exposed mud flats may be contaminated by potential overboard discharge within the current marina area on a flood tide thereby putting the consuming public at risk for bacterial pathogens, chemical contamination and viral pathogens.

- Due to a budget shortfall of $160,000 the Growing Area Classification program is in danger of losing the three new permanent positions that were added by the legislature in spring 2009. The positions are Scientist III, Growing Area Program Manager; Scientist I, Boothbay Harbor and Scientist I, Lamoine. If the budget shortfall cannot be met or exceeded the loss of these positions will have a direct result on the ability of the Department to maintain compliance with the NSSP and will mean decreased services to the shellfish industry and the general shellfish consuming public.

There was one new or emerging trend identified as a result of the 2011 Control of Harvest (Patrol) element evaluation, listed as follows:

- MDMR maintained effective patrol monitoring of the shellfish harvest areas with a vacancy rate of approximately 15% among field officer staff. This has been done only by the individual efforts of a very dedicated workforce. This accomplishment came at a great cost, both financial and the exhaustive effort of a very few. The Bureau is continually hit by cutbacks as the State faces many financial challenges. The Bureau is ever mindful that they will not be able to maintain this level of performance without filling existing vacancies and diligently strives to fill these positions during increasingly stressful fiscal times. During the FY 2011 evaluation period the Bureau of Marine Patrol faced several challenges related to the economic downturn as well as conditions beyond the Bureau's control. There were numerous retirements, resignations, a military deployment and extended medical leaves that stretched the force to its operating limit. Despite these issues the agency continues to meet its obligations relative to checks and enforcement.

F. Unresolved Issues

The Maine Department of Marine Resources has no unresolved issues at this time.

FY 2011

ANNUAL PROGRAM EVALUATION REPORT

OF THE

SHELLFISH SANITATION PROGRAM
DEPARTMENT OF MARINE RESOURCES
STATE OF MAINE

NORTHEAST REGION FIELD OFFICE
FOOD AND DRUG ADMINISTRATION

February 29, 2012